Recall of One Lot of 0.25% Bupivacaine HCL Injection, USP (2.5 MG/ML), 30 ML Single-Dose Vial and One Lot of 0.75% Bupivacaine HCL Injection, USP (7.5 MG/ML), 30 ML Single Dose Vial (09/13)

Hospira Issues a Voluntary Nationwide Recall Due to Presence of Particulate Matter

Contact:
Media
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FOR IMMEDIATE RELEASE - **Sept. 13, 2013** - **LAKE FOREST, Ill.**, - Hospira, Inc. (NYSE: HSP), announced today, on July 12, 2013, it initiated a voluntary nationwide recall to the user level for one lot of 0.25% Bupivacaine HCl Injection, USP (2.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1159-02). An expanded recall was issued on August 29, 2013 for one lot of 0.75% Bupivacaine HCl Injection, USP (7.5 mg/mL), 30 mL Single-dose Vial (NDC 0409-1165-02). Both recalls are due to confirmed customer reports of particulate floating and/or embedded in the glass vial. The particulate was identified as stainless steel ranging in size from 542 microns to 1700 microns in lot 18-136-DK (0.25% bupivacaine) and as iron oxide with an average size of 2000 microns in lot 23-338-DK (0.75% bupivacaine). To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Both products are packaged 25 units per carton/50 units per case in glass teartop vials.

Bupivacaine is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.

The administration of an injectable with the presence of foreign particulates may potentially cause thrombophlebitis, bacteremia, sepsis, and/or endocarditis and death may result. Signs and symptoms could include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea and vomiting. Depending on the particle size, if undetected, it could block administration of the diluted drug to the patient, causing a delay in therapy.

Lot 18-136-DK was distributed August 2012 through September 2012. Lot 23-338-DK was distributed January 2013 through May 2013. Both lots were distributed nationwide to wholesalers/distributors, hospitals and pharmacies.

Product	NDC Number	Lot	Expiration Date
0.25% Bupivacaine HCl Inj., USP (2.5 mg/mL), 30 mL Single-dose Vial	0409-1159-02	18-136-DK*	1JUN2014
0.75% Bupivacaine HCl Inj., USP	0409-	23-338-	1NOV2014

(7.5 mg/mL), 30 mL Single-dose Preservative-Free Vial	1165-02	DK*	

Anyone with an existing inventory should immediately quarantine any affected product and return the product to Stericycle. For additional assistance, call Stericycle at:

Lot	Phone Number (8am to 5pm ET, M-F)
18-136-DK	1-866-240-5364
23-338-DK	1-888-627-2279

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm[1]
- **Regular mail:** use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm[2]
- **Fax:** 1-800-FDA-0178

This recall is being conducted with the knowledge of the FDA.